**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF OKLAHOMA**

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| (1) PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,<br><br>Plaintiff,<br><br>v.<br><br>(1) GLEN MULREADY, in his official capacity as Insurance Commissioner of Oklahoma, and<br><br>(2) the OKLAHOMA INSURANCE DEPARTMENT,<br><br>Defendants. | ) | Civil Action No. CIV-19-977-SLP |

**COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF**

Plaintiff Pharmaceutical Care Management Association ("PCMA"), on behalf of its members, alleges as follows:

**INTRODUCTION**

1. This action seeks a declaration pursuant to 28 U.S.C. § 2201 that the Patient's Right to Pharmacy Choice Act ("the Act") is subject to express preemption under the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et. seq.* ("ERISA") and the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"). The Act impermissibly imposes requirements on central matters of plan management, interferes with the national uniformity of benefits, and acts with respect to Medicare Part D plans. Specifically, the Act restricts a pharmacy benefit manager's

("PBM's") use of preferred pharmacy networks, interferes with a PBM's calculation and disbursement of benefits, and limits a PBM's ability to manage the integrity, quality, and safety of the providers in its network. In so doing, the Act prevents beneficiaries in Oklahoma – workers, their families and seniors - from accessing the full extent of their pharmaceutical benefit plans. The Court should declare the Act preempted and enjoin Defendants from its enforcement.

## JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331 because this case arises under federal law and pursuant to 28 U.S.C. §1367 because all claims not arising under federal law form part of the same case or controversy as the federal law claims.

3. This Court has personal jurisdiction over Defendants because Defendants' principal place of business is within the Western District of Oklahoma.

4. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because the events giving rise to these claims occurred in this district and Defendants reside within the State of Oklahoma.

## THE PARTIES

5. PCMA is the national trade association representing PBMs. PCMA's PBM member companies administer drug benefits for more than 230 million Americans covered by ERISA and non-ERISA health plans. The ERISA benefit plans with which PCMA's members contract include both insured and self-funded benefit plans sponsored

by employers and labor unions. The non-ERISA covered health plans include Medicare Part D prescription drug plans and health plans sponsored by state and local governments that contract directly for PBMs' services. PCMA's principal place of business is in Washington, D.C.

6. PCMA brings this lawsuit on behalf of its members, which include PBMs that administer prescription drug benefits on behalf of health plans and their beneficiaries who reside or purchase pharmaceuticals in Oklahoma.

7. PCMA is a non-profit 501(c)(6) corporation duly organized under the laws of the State of Delaware. PCMA's members include the following PBMs: Abarca Health, CastiaRx, CerpassRx, CVS Health, Envolve Pharmacy Solutions, Express Scripts, Humana Pharmacy Solutions, IngenioRx, Integrated Prescription Management, Magellan Rx Management, Maxor Plus, MedImpact Healthcare Systems, MeridianRx, OptumRx, PerformRx, Prime Therapeutics, Serve You Rx, and WellDyneRx (collectively, the "Members").

8. The claims in this action, which PCMA's Board of Directors has authorized, serve the Members' common interests. None of PCMA's Members has expressed disagreement with the Board's decision to pursue this litigation. PCMA accordingly has Article III standing to sue on behalf of its Members under the doctrine of associational standing. Neither the claims asserted, nor the relief requested, requires the participation of individual Members in this lawsuit.

9. Defendant Glen Mulready is the Insurance Commissioner for the State of Oklahoma ("the Insurance Commissioner"). The Insurance Commissioner's principal place of business is Oklahoma City, Oklahoma. The Insurance Commissioner is being sued solely in his official capacity.

10. Defendant Oklahoma Insurance Department is a department of the government of the State of Oklahoma, headquartered at Five Corporate Plaza, 3625 NW 56th, Suite 100, Oklahoma City, Oklahoma, 73112.

11. Defendants, and those subject to Defendants' supervision, direction, and/or control, are responsible for enforcement of the Act.

## FEDERAL PREEMPTION OF STATE LAWS

12. The Supremacy Clause of the United States Constitution establishes that federal law takes precedence over state laws. U.S. Const. art. VI, cl. 2. State laws are prohibited from interfering with federal law, including the United States Constitution and federal statutes. A state law that interferes with federal law is preempted. Preemption can be either express or implied. Express preemption occurs when Congress explicitly states its intent to preempt state laws that regulate a given topic.

13. ERISA is a comprehensive federal statute that regulates employee benefit plans. 29 U.S.C. §1001, *et. seq*. Congress enacted ERISA to provide "a uniform regulatory regime over employee benefit plans." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 248 (2004). In order to facilitate the efficient administration of benefits nationwide and to ensure that ERISA plans did not face competing or conflicting regimes in each of

the 50 states, Congress included a broad express preemption clause in ERISA. ERISA preempts "any and all state laws insofar as they may now or hereafter relate to any employee benefit plans." 29 U.S.C. §1144(a).

14. In 2003, Congress established the Medicare prescription drug benefit, referred to as Medicare Part D. Medicare Part D subsidizes the costs of prescription drugs for Medicare beneficiaries, including U.S. citizens and lawful permanent residents age 65 and older and certain younger people with disabilities. Medicare Part D consists of a comprehensive statutory and regulatory scheme that aims to balance costs (both to the government and to beneficiaries) with access.

15. Medicare Part D employs "a market-based model under which marketplace competition ensures that enrollees receive low prices for prescription drugs." 70 Fed. Reg. 4194, 4244. All Medicare Part D beneficiaries must receive their benefits through a nongovernmental entity, the Medicare Part D plan sponsor; there is no mechanism to allow pharmacists to bill Medicare directly for Medicare Part D covered drugs. 42 U.S.C. §1395w-101(a)(1)(A). Part D plan sponsors, through PBMs, negotiate with pharmacies for competitive pricing and service arrangement. *See* 42 U.S.C. §1395w-102(d) (requiring Part D plan sponsors to provide Part D beneficiaries "with access to negotiated prices"). In turn, Part D plan sponsors compete for beneficiaries by offering different coverage options and lower out-of-pocket expenses.

16. In order to prohibit state interference in the administration of the Medicare Part D benefit, Congress adopted a broad express preemption provision for state laws with respect to Part D plans. That preemption provision states:

> "The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Part D plans] which are offered by [Part D sponsors] under this part." 42 U.S.C. §1395w-26(b)(3).

## FACTS

A. The Prescription Drug Market and PBMs' Role

17. Many Oklahoma residents receive their prescription drug benefits through health plans, including self-funded and insured health benefit plans sponsored by employers and employee organizations, health plans offered by nonprofit hospital or medical service organizations, health plans sponsored by unions, federal and state government plans, and publicly funded programs including Medicare Part D and Medicaid (collectively "health plans"). Approximately 3.4 million of Oklahoma's 3.9 million residents are covered by public or private insurance. Of the insured, approximately 1.7 million are covered by employer sponsored health plans. Just over 500,000 Oklahomans have prescription drug coverage through the Medicare program.

18. When a health plan beneficiary fills a prescription at the pharmacy counter, the resulting transaction is the product of several pre-existing contractual relationships. At least five key players are involved in enabling a plan beneficiary to purchase a prescription drug: pharmacies, wholesalers, manufacturers, PBMs, and health plans. A

graphical description of the prescription drug supply and payment chain is attached as Exhibit 1.

- ***Pharmacies*** purchase drugs or drug ingredients from national and/or regional ***wholesalers,*** who in turn, purchase drugs and drug ingredients from ***manufacturers***.
- ***PBMs*** contract with ***pharmacies*** to create pharmacy networks that guarantee beneficiaries access to their pharmaceutical benefits at negotiated, standardized prices.
- At the same time, ***PBMs*** use their purchasing power to negotiate rebates with ***manufacturers*** that drive down total prescription drug costs for health plans.
- ***Health plans*** contract with ***PBMs*** to leverage the PBMs' economies of scale in managing their prescription drug benefits.

19. Health plans will choose from the various options offered by the PBM in order to accomplish their plan goals and meet the needs of their beneficiaries. For example, some plans are primarily concerned about reducing the costs of their pharmacy benefits and implement structures with less flexibility or multi-tiered networks to achieve that goal. These plans may choose to use preferred pharmacy networks or otherwise limit the pharmacies to which plan beneficiaries can go for maintenance medication in order to leverage claims-volume for better prices. Other plans, however, are willing to increase costs in order to provide more service options. Plans offering a specialty pharmacy benefit may prioritize their members' access to a specifically-accredited specialty pharmacist over proximity to the member, and may craft their specialty pharmacy offerings accordingly. Medicare Part D plans may create a plan structure that matches the

specialized needs of seniors, such as a structure that prioritizes inexpensive and convenient refills of maintenance prescription drugs that members take regularly.

20. PBMs offer health benefit plans a variety of services to manage their prescription drug benefits. PBMs process claims and make disbursements. In addition, health plans engage PBMs to increase access for beneficiaries, drive value, and improve quality of care. Some of the tools PBMs use to further these plan goals include:

a. *Pharmacy Networks*

i. PBMs typically design retail pharmacy networks and negotiate with pharmacies to set a competitive rate at which the PBM will reimburse a pharmacy for each prescription that it fills. These networks are essential to PBMs' contracts with health plans because they allow PBMs to help ensure that a health plan's members – workers, their families and seniors – will receive adequate service, including accessibility at the level required by the Centers for Medicare & Medicaid Services ("CMS") for Medicare Part D plan members.

ii. The pharmacies in a PBM's network fill prescriptions for health plan members using prescription drugs pharmacies have purchased directly from wholesalers or manufacturers. When a health plan member goes to a pharmacy to fill a prescription, the pharmacy confirms with the PBM the applicable plan design for the plan member in order to determine coverage and copayment information. After the prescription is filled, the PBM reimburses the pharmacy at a contractually agreed to negotiated rate minus the copay collected by the pharmacy from the plan participant.

iii. In order to offer beneficiaries and plan sponsors additional cost-savings, PBMs also create preferred pharmacy networks. Preferred pharmacy networks are networks of pharmacies where plans and beneficiaries pay a lower amount for a drug than at a pharmacy in the standard network.

iv. A preferred pharmacy network provides value to beneficiaries and plan sponsors. Beneficiaries benefit from lower copays and other cost sharing discounts for drugs obtained at a pharmacy in the preferred pharmacy network. These lower copays and other cost-sharing discounts incentivize beneficiaries to purchase drugs from preferred pharmacies. Health plans benefit because pharmacies agree to lower reimbursement rates in exchange for participation in the preferred pharmacy network. Pharmacies agree to participate in a preferred network in order to obtain a higher volume of beneficiaries.

b. *Quality of Care Initiatives*

*i.* PBMs improve care quality and safety by using benefits and claims data and technological tools to reduce the risk of drug duplication and dangerous drug-to-drug interactions. PBMs maintain IT systems, pharmacy help lines, and benefit manuals that assist pharmacies in processing claims accurately and efficiently while reducing medical errors.

*ii.* PBMs often require pharmacies to satisfy specific safety and quality criteria to participate in their networks to improve the quality of care provided to beneficiaries.

*iii.* PBMs also use credentialing and enhanced accreditation standards to evaluate a pharmacy's ability to provide high-value specialty services and to ensure only qualified pharmacies provide care to beneficiaries. These specialty pharmacies manage drug regimens for patients with complex, chronic, or rare medical conditions such as multiple sclerosis, hepatitis C, cystic fibrosis, and hemophilia. Because of unique handling requirements and the complexities of caring for patients with complex, chronic, or rare conditions, the average pharmacy is often ill equipped to dispense specialty pharmaceuticals and provide appropriate levels of patient care. PBMs' enhanced accreditation standards help ensure that patients with the most challenging drug regimens receive care from the most qualified individuals.

*iv.* PBMs conduct drug utilization review programs – ongoing reviews of what drugs a provider prescribes, a pharmacist dispenses, and a plan member uses – and implement patient adherence programs to help patients stick to their prescription regimens. Both programs improve clinical outcomes while simultaneously managing prescription volume and expenditures.

c. *Obtaining Value for Beneficiaries and Health Plans*

i. PBMs use several tools to encourage dispensing of lower-cost generics and less expensive brands, including formularies, tiered cost sharing, prior authorization and step therapy protocols, generic incentive programs, consumer education, and physician outreach, in order to improve care and lower costs.

ii. PBMs review pharmacy claims, including after the point-of-sale and after initial payments have been made, to ensure that benefits are disbursed in accordance with the terms of the plan. Often, changes in individual reimbursements are necessary due to unintentional processing errors when the pharmacist originally submitted the claim. PBMs will recoup payments made in excess of the contractually agreed to rate with the pharmacy.

21. Because PBMs provide some of the best tools in the marketplace to control prescription drug costs and maximize patient outcomes, nearly all plans – public and private, ERISA and Medicare Part D – providing prescription drug coverage utilize PBMs' services.

22. Health plans will select a PBM through a competitive bidding process, in which PBMs submit bids in response to requests for proposals from a health plan. PBMs compete on both financial and service terms. PBMs seek to differentiate themselves to potential customers on drug prices, administrative fees and other charges for a PBM's services, the breadth of the PBM's pharmacy network, and other services PBMs offer to drive value and improve beneficiaries' outcomes.

23. Health plans individually negotiate their contracts with PBMs. In these contracts, PBMs make various guarantees related to services and drug pricing, including obligations for the PBM to offer certain pharmacy networks. A health plan's contract with a PBM will also typically include performance incentives for the PBM related to efficient and accurate claims processing.

B. The Patient's Right to Pharmacy Choice Act

24. On May 21, 2019, Governor Kevin Stitt signed House Bill 2632 of the 2019 Regular Session of the Oklahoma State Legislature. House Bill 2632 created the Patient's Right to Pharmacy Choice Act. A copy of House Bill 2632 of the 2019 Regular Session of the Oklahoma State Legislature is attached as Exhibit 2. The Act takes effect on November 1, 2019.

25. Contrary to its name, the Act does not focus on patient rights. Rather, it operates primarily to weaken competition among pharmacies by limiting the ability of PBMs to offer their cost-saving and quality assurance initiatives within the State of Oklahoma.

26. The Act defines a PBM as "a person that performs pharmacy benefits management and any other person acting for such person under contractual or employment relationship in the performance of pharmacy benefits management for a managed-care company, non-profit hospital, medical service organization, insurance company, third-party payor or a health program administered by a department of this state." 36 O.S. §6960(3).

27. The Act places several significant restrictions on PBMs:

a. *Provisions Regulating Pharmacy Networks (collectively, the "Network Restrictions")*

i. The Act imposes pharmacy access standards for both a PBM's standard retail pharmacy network and preferred pharmacy network. 36. O.S. §6961(A) ("Pharmacy Access Standards"). For urban, suburban, and rural service areas, it sets a

percentage of beneficiaries that must live within a set geographic distance from a network pharmacy. *Id.* It also prohibits PBMs from using mail-order pharmacies to meet the Pharmacy Access Standards. 36 O.S. §6961(B). The Oklahoma Insurance Department is authorized to review and approve these networks. 36 O.S. §6962(A).

ii. The Act requires a PBM to allow any pharmacy to participate in any pharmacy network at preferred participation status if the pharmacy is willing to accept the terms and conditions the PBM has established for other pharmacies as a condition of preferred network participation status. 36 O.S. §6962(B)(4) ("Any Willing Provider Provision").

iii. The Act prohibits PBMs from including the name of any pharmacy, hospital, or other providers on mail, ID cards, or any other materials unless the materials specifically lists all pharmacies, hospitals, and providers participating in the preferred and non-preferred pharmacy networks. 36 O.S. §6961(D) ("Promotional Material Prohibition").

iv. The Act provides that a "health insurer or PBM shall not require or incentivize using any discounts in cost-sharing or a reduction in copay or the number of copays to individuals to receive prescription drugs from an individual's choice of in-network pharmacy." 36 O.S. §6963(E) ("Cost-Sharing Discount Prohibition").

v. The Act prohibits health insurers or PBMs from restricting an individual's choice of in-network provider for prescription drugs, 36 O.S. §6963 (D), or requiring beneficiaries to use pharmacies that are directly or indirectly owned by the

PBM, 36 O.S. §6961(C) ("Affiliated Pharmacy Service Provision"), including for the limited purposes of refills or specialty drugs (together, "Beneficiary Direction Provisions").

vi. The Network Restrictions significantly curtail PBMs' abilities to use preferred pharmacy networks. A PBM will be limited in its ability to leverage increased volume in exchange for a pharmacy's participation in a preferred pharmacy network, and beneficiaries will no longer have adequate access to lower copays and other cost sharing discounts for using preferred pharmacies. As a result, pharmacies will have less incentive to lower prices for plans and beneficiaries.

b. *Provisions Regulating Claims Processing and Disbursements (collectively, the "Claims Processing Restrictions")*

i. The Act prohibits a PBM from charging a pharmacy a fee related to the adjudication of a claim, including without limitation, a fee for: (1) the submission of a claim, (2) enrollment or participation in a retail pharmacy network, or (3) the development or management of claims processing services or claims payment services related to participation in a retail pharmacy network. 36 O.S. §6962(B)(2) ("Service Fee Prohibition").

ii. The Act prohibits a PBM from retroactively denying or reducing a reimbursement for a covered service after returning a paid claim response as part of the adjudication of the claim, unless the original claim was submitted fraudulently or to correct errors identified in an audit in compliance with 59 O.S. §§ 356.2 and 356.3. 36 O.S. §6962(B)(6) ("Claims Adjustment Prohibition").

iii. The Act prohibits a PBM from reimbursing a pharmacy less than the amount the PBM reimburses a pharmacy owned by or under common ownership with the PBM for providing the same covered services. 36 O.S. §6962(B)(3) ("Affiliated Pharmacy Reimbursement Provision").

iv. The Act requires a PBM to establish and maintain an electronic claim inquiry processing system using the National Council for Prescription Drug Programs' current standards to communicate information to pharmacies submitting claim inquiries. 36 O.S. §6962(C)(3) ("Electronic Claim Inquiry Provision").

v. The Claims Processing Restrictions interfere with the methodology by which PBMs reimburse pharmacies for prescription drug claims. The Service Fee Prohibition will prevent PBMs from collecting fees that are used to implement their quality of care initiatives. The Claims Adjustment Prohibition will impede a PBM's ability to process claims in accordance with the terms of the health benefit plan.

c. *Provisions Regulating Network Integrity, Quality, and Safety (collectively, the "Integrity and Quality Restrictions")*

i. The Act prohibits a PBM from denying, limiting, or terminating a pharmacy's contract based on the employment status of any employee who has an active license to dispense, despite probation status. 36 O.S. §6962(B)(5) ("Pharmacy Termination Prohibition").

ii. The Act prohibits a PBM from failing to make any payment due to a pharmacy for a covered service in the event a PBM terminates a pharmacy from its network. 36 O.S. §6962(B)(7) ("Terminated Pharmacy Payment Provision").

iii. The Integrity and Quality Restrictions interfere with a PBM's ability to direct beneficiaries to qualified pharmacists. Instead, beneficiaries may seek services from pharmacists who do not meet a PBM's quality standards, either because they are facing disciplinary proceedings or because they lack specialized expertise to work with patients with complex or rare conditions.

d. *Provisions Regarding Network Oversight (collectively, "Health Insurer Oversight Provisions")*

i. The Act requires a health insurer to be responsible for monitoring all activities carried out by, or on behalf of, the health insurer under the Act. 36 O.S. §6963 ("Health Insurer Monitoring Requirement").

ii. A health insurer's pharmacy and therapeutics committee is required to establish a formulary of both generic and brand name drugs to identify drugs that offer the greatest overall value. 36 O.S. §6964(A) ("Formulary Requirement").

iii. Together, the Health Insurer Oversight Provisions interfere with the contractual relationship between health plans and their PBMs.

28. The Act authorizes the Insurance Commissioner to enforce the Act. The Insurance Commissioner is authorized to conduct investigations and review PBM files and records as part of his enforcement authority. 36 O.S. § 6965(A)-(B).

C. <u>The Act Harms Beneficiaries, Health Benefit Plans, and PBMs</u>

29. The Act interferes with PBMs' methods of doing business and lessens their ability to differentiate their services, damaging competition and diminishing their value to plan members – workers, their families, and seniors.

30. First, the Act interferes with key aspects of plan design and benefit packages that PBMs and health plans offer to beneficiaries. For example, the Act impedes PBMs from offering discounts to plan members for using preferred pharmacies. PBMs and the health benefit plans they serve must either: 1) restructure their benefit packages nationwide to limit cost-sharing discounts, 2) create unique plan designs for beneficiaries purchasing drugs in Oklahoma that limit cost-sharing discounts or 3) be subject to penalties in Oklahoma, including fines and having licensing revoked.

31. Second, the Act prevents PBMs from managing prescription drug reimbursements in accordance with the terms of the health benefit plan. The Integrity and Quality Restrictions prevent PBMs from providing health plans and their beneficiaries with the quality of care and oversight that they have been contracted to provide. In addition, the Claims Adjustment Prohibition strictly limits PBMs' abilities to collect overpayments related to unintentional claims processing errors. A PBM's ability 1) to manage the quality of its pharmacy network, and 2) to accurately adjudicate and disburse claims, is central to a PBM's competitive position in the market. The Act will lessen a PBM's ability to differentiate its services, damaging its competitive position, and lowering its value to health plans.

32. Third, the Act interferes with a beneficiary's access to the quality and safety standards currently necessary for inclusion in the PBM's pharmacy network. For example, the Act prevents a PBM from directing a patient with a complex, chronic condition to a pharmacy with the expertise to meet that patient's needs. Further, the Act

prevents a PBM from terminating a pharmacy contract when a pharmacist has been placed on probation. Without such guidance, a patient may unknowingly fill a prescription at a pharmacy that lacks the requisite skills or quality standards for inclusion in the PBM's network.

33. The Act also restricts PBM business practices that drive value for health plans and their beneficiaries. The Act disrupts the market-based negotiations between PBMs and pharmacies and the tools PBMs use to contain and lower prescription drug costs. PBMs and health plans will face higher costs for prescription drugs as a result.

34. By interfering with a PBM's method of doing business, the Act, in turn, harms plan members – workers, their families, and seniors. For example, the Pharmacy Network Restrictions, including the Cost-Sharing Discount Prohibition, interfere with plan members accessing the full extent of their prescription drug benefits in Oklahoma. Beneficiaries in Oklahoma will not have access to the copay and cost-sharing discounts that are available under their plan in the other 49 states.

D. The Oklahoma Insurance Department Emergency Regulations

35. On October 22, 2019, Governor Stitt signed Emergency Regulations adopted by the Insurance Commissioner to implement the Act. a copy of which is attached as Exhibit 3. The Emergency Regulations go into effect on November 1, 2019.

36. Among its other provisions, the Emergency Regulations state that the Act "draws no distinction between regular or specialty drugs, both being prescription

medications, therefore, specialty drugs fall within the contemplation of the act." Okla. Admin. Code §365:25-29-7.1(a)(2) ("Specialty Drugs Rule").

37. The Emergency Regulations also prohibit PBMs from including the name of any pharmacy, hospital, or other provider unless it specifically lists all pharmacies, hospitals, and providers. OAC §365:25-29-7.1(a)(3) ("Promotional Materials Rule").

38. Further, the Emergency Regulations require a health insurer utilizing the services of a PBM to be responsible for approving all contractual documents utilized by its contracted PBMs and its retail pharmacy network to ensure compliance with the Act. OAC §365:25-29-9(c)(1) ("Contract Approval Rule").

39. The Specialty Drugs Rule, the Promotional Materials Rule, and the Contract Approval Rule each exceed the scope of the Insurance Commissioner's authority under the Act. In addition, these rules interfere with a PBM's ability to manage a health plan's pharmacy benefits.

E. A Justiciable Controversy Now Exists Between PCMA and Defendants

40. An actual case or controversy has arisen between the parties. The Act and the Emergency Regulations will become effective on November 1, 2019. As such, the claims raised by PCMA in this complaint are fit for judicial decision today and are not speculative or contingent. In order to comply with the Act, PCMA's members will be forced immediately to revise their business practices, including their preferred pharmacy networks and processes in place to review claims and make disbursements. Such injury to

the Members would make out a justiciable case had the Members themselves brought suit.

## CLAIMS FOR RELIEF

### COUNT 1

### (ERISA PREEMPTION)

41. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 40 if fully set forth herein.

42. The Act, the Specialty Drugs Rule, the Promotional Materials Rule, and the Contract Approval Rule "relate to" an employee benefit plan because they (1) impose requirements on those PBMs serving "third-party payor[s]," which facially encompasses ERISA-covered health plans, (2) regulate central matters of plan management, (3) interfere with the national uniformity of benefits, and (4) cause an acute economic impact that forces an ERISA plan to adopt a substantive coverage scheme.

43. The Act, the Specialty Drugs Rule, the Promotional Materials Rule, and the Contract Approval Rule regulate PBMs administering pharmacy benefits on behalf of health plans covered by ERISA and therefore functions as a regulation of such ERISA-covered plans.

44. Accordingly, the Act, the Specialty Drugs Rule, the Promotional Materials, and the Contract Approval Rule are expressly preempted by ERISA.

### COUNT 2

### (MEDICARE PART D PREEMPTION)

45. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 40 as if fully set forth herein.

46. The Federal government and CMS have established standards that comprehensively regulate the operations of Medicare Part D plans and by extension, PBMs serving those plans. *See* 42 C.F.R. §423.505(i) (requirements for contracts between Medicare Part D plan sponsors and first-tier entities, such as PBMs). For example, the MMA and its implementing regulations include:

a. An express authorization to establish preferred pharmacy networks where beneficiaries can obtain reduced copayments or coinsurance, *see* 42 C.F.R.§423.120(a)(9);

b. A network access requirement that dictates the number of pharmacies that must be included in a Part D plan's pharmacy network and the inclusion of mail-order pharmacies in those networks, *see* 42 C.F.R. §§423.120(a)(1)&(3);

c. An any willing provider requirement, which requires a Part D sponsor to contract with any pharmacy that meets the Part D sponsor's terms and conditions for participation in the plan's standard, non-preferred network, *see* 42 C.F.R. §423.120(a)(8) and 42 C.F.R. §423.505(b)(18);

d. A requirement guaranteeing beneficiaries access to negotiated prices, 42 U.S.C. §1395w-102(d)(1)(A), and prohibiting the government from interfering with price negotiations among pharmacies and Medicare Part D plans and from instituting a price

structure for the reimbursement of Medicare Part D drugs, *see* 42 U.S.C. §1395w-111(i)(1)-(2);

e. Requirements related to dissemination of plan information to beneficiaries, including the participation of pharmacies in the Part D plan's network, *see* 42 C.F.R. §423.128.

f. Requirements for Part D sponsors to monitor the regulatory compliance of PBMs with whom they contract, *see* 42 C.F.R. §423.505(i).

47. The Act, the Specialty Drugs Rule, the Promotional Materials Rule, and the Contract Approval Rule are laws with respect to Medicare Part D plans because they specifically regulate health plans, including Medicare Part D plans, either directly or through PBMs. Although not necessary for purposes of the express preemption requirement, the Act, the Specialty Drugs Rule, the Promotional Materials Rule, and the Contract Approval Rule also regulate Part D plans in areas where the federal government has expressly established standards governing these plans.

48. Accordingly, the Act, the Specialty Drugs Rule, the Promotional Materials Rule, and the Contract Approval Rule are expressly preempted by Medicare Part D.

**COUNT 3**

**(For Ultra Vires Agency Action) (Alternative)**

49. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 40 as if fully set forth within.

50. The Oklahoma Administrative Procedures Act requires this Court to hold unlawful and set aside any rule that exceeds the statute authorizing or controlling its issuance. 75 O.S. §306.

51. The Specialty Drugs Rule, the Promotional Materials Rule, and the Contract Approval Rule exceed the Defendants' authority in the Act as conferred upon Defendants by the Oklahoma Legislature.

52. Defendants' ultra vires action will cause Plaintiff substantial and irreparable harm, as described above. Therefore, Plaintiff is entitled to the declaratory and injunctive relief requested herein.

## REQUEST FOR RELIEF

WHEREFORE, PCMA respectfully prays that this Court:

(1) declare that the Act, the Specialty Drugs Rule, the Promotional Materials Rule, and the Contract Approval Rule are preempted by the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§1001 *et seq.*,;

(2) declare that the Act, the Specialty Drugs Rule, the Promotional Materials, Rule, and the Contract Approval Rule are preempted by the Medicare Part D statute, 42 U.S.C. §1395w-112(g) and 1395w-26(b)(3);

(3) alternatively, to the extent the Act is not preempted, declare that the Specialty Drugs Rule, the Promotional Materials Rule, and the Contract Approval Rule are invalid because they exceed the scope of Defendants' authority under the Act;

(4) grant preliminary and permanent injunctive relief enjoining Defendants and his agents from taking any action under or to enforce the Act; and

(5) grant Plaintiff such additional or different relief as it deems just and proper.

Respectfully submitted,

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